

**REMARKS**

Claims 1-5, 7, 10, 15-16, 19-20, and 23-30 are pending; claims 31-34 are newly added.

**THE AMENDMENTS**

The new claims are intended in part to respond to the election requirement in the pending Office Action, as well as to address particular embodiments of the invention. The election, discussed further below, is made with traverse. As directed by the Office Action, Applicants elect a specific sex hormone - testosterone; a specific polycarboxylic polymer - polycarbophil; and a specific water soluble polymer - carbomer 974P. These specific components are included in claims 32 and 34. Support for these particular components is found in the specification, for example at Table 1, on page 18.

The amendments to the pre-existing claims are intended to further clarify the intended scope of the claims, consistent with the specification and arguments of record. The term "bioadhesive" is added to the independent claims, merely to clarify the fact that all of the contemplated compositions and methods involve bioadhesion of the composition. Support for this term is found in the specification, for example at page 1, lines 3-10. The term "water swellable" is added to claim 26, with regard to the description of the water insoluble polymer. Support for this term is found in the specification, for example, at page 7, lines 29-33; and page 11, line 29 to page 12, line 2. Bioadhesive, water insoluble, water swellable, cross-linked polycarboxylic polymers have -- by definition -- the properties needed to provide the desired, controlled, sustained release of the treating agent, the progressive hydration, and the extended bioadhesion, as well as gelification or swelling to help prevent asphyxiation by a patient using a buccal formulation.

These amendments and new claims are not intended to narrow or otherwise change the scope of any of the terms of any of the claims, for any patentability or other reason. No new matter is added by these amendments and new claims.

Marked-up copies of the amendments are attached as Appendix A; a complete set of all pending claims is attached as Appendix B.

### **THE ELECTION REQUIREMENT AND APPLICANT'S ELECTION**

Applicants hereby elect as directed by the Office Action, with traverse. As directed, Applicants elect a specific sex hormone - testosterone; a specific polycarboxylic polymer - polycarbophil; and a specific water soluble polymer - carbomer 974P. These specific components are included in claims 32 and 34. Support for these components is found in the specification, for example at Table 1, on page 18.

Applicants traverse the election requirement as improper and unwarranted. First, the election requirement required that a new species claim be created and submitted, rather than that Applicants elect one of several pending claims or groups of claims. Second, the description used with reference to the generic claims is overly broad and incorrect. And third, the several pending generic claims are not patentably distinct, and would not require any additional searching, as they all address bioadhesive, progressive hydration delivery of a treating agent through a composition containing two additional specific pharmaceutical components -- one very narrow, and one somewhat broader.

#### **1. The Election Requirement Was Improper**

Applicants respectfully that the election requirement was improper, because in effect it required Applicants to submit at least one additional claim that was not already of

record in the application. The pending claims are generic, and the election effectively required submission and selection of at least one species claim.

However, "[w]hen only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary." MPEP § 809.02(d). As discussed further below, even the generic claims are rather narrow, and so do not cover such a multiplicity of species as to require an unduly extensive and burdensome search.

Nevertheless, in order to facilitate further prosecution of this application, Applicants submit additional claims 32 and 34, which, as discussed above, include the specific designations as required by the election requirement.

## **2. The Generic Claims Are Narrower Than Recited In The Election Requirement**

The election requirement directed selection of a "specific polycarboxylic polymer." However, all pending claims are specifically limited to including a bioadhesive, water insoluble, water swellable cross-linked polycarboxylic polymer -- a vastly narrower class of polymers. Only those relatively few polymers that are described in this specific manner possess the particular properties crucial to the instant invention -- sustained release of a treating agent; progressive hydration; extended bioadhesion; and gelification or swelling to help prevent asphyxiation by a patient using a buccal formulation.

The independent claims address progressive hydration delivery of an active ingredient that is a sex hormone (or that specifically is testosterone), and include a water soluble polymer. The category of treating agents that are sex hormones is relatively narrow. Water soluble polymers are not especially limiting, though they serve the purpose

interchangeably as long as they are used in combination with the very specific other polymer.

Most importantly, requiring all of these elements at one time -- (1) progressive hydration and thus sustained release; (2) a treating agent that is a sex hormone (or that is testosterone); using a combination of (3) a bioadhesive, water insoluble, water swellable cross-linked polycarboxylic polymer and (4) a water soluble polymer; covers only a very specific, very narrow set of potential compositions. Consistent with this position is the fact that there is no prior art of record -- or otherwise known to Applicants -- that discloses or teaches the combination of the two particular types of polymers to provide a progressive hydration formulation, let alone in further combination specifically with a sex hormone.

### **3. The Generic Claims All Relate To The Same General Invention**

The pending generic independent claims all relate to the same basic invention -- methods and compositions involving a progressive hydration bioadhesive formulation for release of a treating agent that is a sex hormone, including specifically a bioadhesive, water insoluble, water swellable, and cross-linked polycarboxylic polymer and a water soluble polymer. As discussed above, the former polymer description is very narrow, the latter is more general. But the specific combination, which is not found in the art of record, is what provides the desired benefits and the claimed invention.

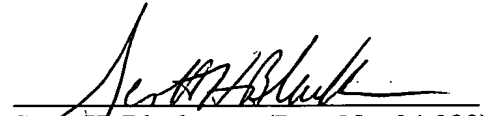
### **Conclusion**

In light of these remarks, Applicants respectfully request reconsideration and withdrawal of the election requirement, and allowance of all claims.

No fee is believed to be due for this submission. If there are any fees due, please charge the required fees to Winston & Strawn Deposit Account No. 501-814.

Respectfully submitted,

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APPENDIX A

**The Version with Markings to Show Changes made of amended claims 1, 10, 23, and 26 read as follows:**

1. (Four times amended) A bioadhesive, controlled, sustained release progressive hydration pharmaceutical composition in the form of a tablet, comprising:

an effective amount of an active ingredient that is a sex hormone,  
a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer, and  
a water soluble polymer,

wherein said composition is formulated in a dry state to deliver, upon administration of said tablet to a mucosal surface of a mammal, said active ingredient to the bloodstream of said mammal.

10. (Twice amended) A method of delivering testosterone to a mammal, comprising administering said testosterone via a bioadhesive, progressive hydration composition through a mucosal surface of the mammal, wherein the composition comprises:

a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer,  
a water soluble polymer, and  
said testosterone,

and wherein said method provides a blood serum concentration ration of testosterone to 5 $\alpha$ -dihydrotestosterone (DHT) of about 10 to 1 or greater in the bloodstream of said mammal.

23. (Twice amended) A bioadhesive, progressive hydration pharmaceutical composition comprising:

testosterone,  
a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer,  
and a water soluble polymer,

wherein said composition is formulated to progressively hydrate and to deliver a therapeutically effective amount of said testosterone to the bloodstream of a mammal through a mucosal surface of the mammal.

26. (Amended) A bioadhesive, controlled, sustained release progressive hydration composition for delivering testosterone to the bloodstream of a mammal, comprising:

a bioadhesive, water insoluble, water swellable cross-linked polycarboxylic polymer,  
a water soluble polymer,  
and testosterone,

wherein said composition is formulated to deliver said testosterone through a mucosal surface of the mammal, and to provide a blood serum concentration ratio of testosterone to 5 $\alpha$ -dihydrotestosterone (DHT) of about 10 to 1 or greater in the bloodstream of said mammal.

APPENDIX B

**Bioadhesive Progressive Hydration Tablets**  
**Pending Claims: 1-5, 7, 10, 15-16, 19-20, 23-34**

1. (Four times amended) A bioadhesive, controlled, sustained release progressive hydration pharmaceutical composition in the form of a tablet, comprising:

an effective amount of an active ingredient that is a sex hormone,  
a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer, and  
a water soluble polymer,

wherein said composition is formulated in a dry state to deliver, upon administration of said tablet to a mucosal surface of a mammal, said active ingredient to the bloodstream of said mammal.

2. The composition of claim 1, wherein said active ingredient is present in about 50% by weight or less.

3. The composition of claim 1, wherein active ingredient is testosterone or progesterone.

4. The composition of claim 3, wherein said composition is formulated to deliver said active ingredient via the mammal's vaginal cavity.

5. The composition of claim 3, wherein said composition is formulated to deliver said active ingredient via the mammal's buccal cavity.

7. (Twice amended) A method of delivering to a mammal a sex hormone, comprising administering said sex hormone via a progressive hydration bioadhesive composition to a mucosal surface of the mammal, wherein said composition is formulated as a dry tablet that includes

(a) said sex hormone,  
(b) a bioadhesive, water insoluble, water swellaable cross-linked polycarboxylic polymer, and  
(c) a water-soluble polymer.

10. (Twice amended) A method of delivering testosterone to a mammal, comprising administering said testosterone via a bioadhesive, progressive hydration composition through a mucosal surface of the mammal, wherein the composition comprises:

a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer,  
a water soluble polymer, and  
said testosterone,



and wherein said method provides a blood serum concentration ratio of testosterone to 5 $\alpha$ -dihydrotestosterone (DHT) of about 10 to 1 or greater in the bloodstream of said mammal.

15. (Amended) The composition of claim 1, wherein said composition is formulated to deliver said active ingredient via the mammal's nasal cavity.

16. (Amended) The composition of claim 1, wherein said composition is formulated to deliver said active ingredient via said mammal's rectal cavity.

19. The method of claim 10, wherein said composition is administered through the mammal's buccal cavity.

20. The method of claim 10, wherein said composition is formulated is administered through the mammal's vaginal cavity.

23. (Twice amended) A bioadhesive, progressive hydration pharmaceutical composition comprising:

testosterone,  
a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic  
polymer,  
and a water soluble polymer,

wherein said composition is formulated to progressively hydrate and to deliver a therapeutically effective amount of said testosterone to the bloodstream of a mammal through a mucosal surface of the mammal.

24. The pharmaceutical composition of claim 23, wherein said composition is formulated to deliver said testosterone via the mammal's buccal cavity.

25. The pharmaceutical composition of claim 23, wherein said composition is formulated to deliver said testosterone via the mammal's vaginal cavity.

26. (Amended) A bioadhesive, controlled, sustained release progressive hydration composition for delivering testosterone to the bloodstream of a mammal, comprising:

a bioadhesive, water insoluble, water swellaable cross-linked polycarboxylic  
polymer,  
a water soluble polymer,  
and testosterone,

wherein said composition is formulated to deliver said testosterone through a mucosal surface of the mammal, and to provide a blood serum concentration ratio of testosterone to 5 $\alpha$ -dihydrotestosterone (DHT) of about 10 to 1 or greater in the bloodstream of said mammal.

27. The controlled, sustained release progressive hydration composition of claim 26, wherein said composition is formulated to deliver said testosterone via the mammal's buccal cavity.

28. The controlled, sustained release progressive hydration composition of claim 26, wherein said composition is formulated to deliver said testosterone via the mammal's vaginal cavity.

29. The method of claim 7, wherein said mucosal surface is the mammal's vaginal cavity.

30. The method of claim 7, wherein said mucosal surface is the mammal's buccal cavity.

31. A bioadhesive, progressive hydration pharmaceutical composition comprising:  
  
testosterone,  
polycarbophil,  
and a water soluble polymer,

wherein said composition is formulated to progressively hydrate and to deliver said testosterone to the bloodstream of a mammal through a mucosal surface of the mammal.

32. The composition of claim 31, wherein the water soluble polymer is carbomer 974P.

33. A method of administering testosterone to a mammal, comprising delivery of said testosterone via a progressive hydration bioadhesive composition to a mucosal surface of said mammal, wherein said composition includes

- (a) said testosterone,
- (b) polycarbophil, and
- (c) a water soluble polymer.

34. The method of claim 33, wherein said water soluble polymer is carbomer 974P.